

# Regulatory Standards Division AMA-200

Document #

QP 210

Revision

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Title: Control Of Documents

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REVISION HISTORY					
Rev	Description of Change	Author	Effective Date		
Α	Original	JLA	05/28/2003		
1	Clarify System and Product level approvals, edit typos	JLA	01/16/2004		

REFERENCE DOCUMENTS					
<b>Document Number</b>	Document Title				
QMS-200	AMA-200 Quality Systems Manual				

Documents referenced in this procedure are applicable to the extent specified herein.

### 1. Purpose

This procedure defines the implementation and maintenance of a document control system in accordance with the AMA-200 Quality System Manual.

# 2. Scope

This procedure applies to the control of documents and records pertaining to the AMA-200 Quality System. AMA-200 Quality Manuals, Procedures, Work Instructions and associated documents shall be developed and maintained using this procedure.

## 3. Definitions and Acronyms

Administrative Change

Administrative Change	impact its basic intent (e.g., grammatical, template formatting, typo-fixes, etc.).
Author	Person that creates or revises a document.

Data Quality System information used to control the process that affects the final product (e.g. reference values,

benchmarks)

DCR Package DCR (QF 210) and any supporting documentation.

Document Quality System policy, procedure, work instruction,

manual, or associated data in any media which is used to control the processes that affect the quality of the final

Any clerical change to a document or data that does not

product



**Document Change** Form used to create or change a document (QF 210). Request (DCR) Major Change Any change to a document that impacts a system level or product line level process. Master List List which identifies the Quality System documents and includes current revision status. Minor Change Any change to a document that does not impact a system level or product line level process. Originator Any person who initiates a DCR. **Project Coordinator** Any person responsible for the authoring the output of a project team. Review Team Persons assigned by the Management Representative to review and comment on DCR(s).

#### 4. Flowchart

There is no flowchart required for this document.

### 5. Responsibilities

- 5.1 The **Originator shall**:
  - 5.1.1 Complete Document Change Request (DCR) Step 1.
  - 5.1.2 Submit the DCR Package to the Management Representative.
- 5.2 The Management Representative (for system level documents) or Branch Manager (for Product level documents) shall:
  - Manager (for Product level documents) shall:

    5.2.1 Assign an Author or Project Coordinator.

    - 5.2.2 Assign a Review Team (if applicable).
    - 5.2.3 Determine document priority.
    - 5.2.4 Approve, re-approve or disapprove documents.
    - 5.2.5 Complete DCR Steps 3 -- 6 as required by the DCR.
    - 5.2.6 Submit the final DCR Package to the Management Representative for appropriate action if Product level.
    - 5.2.7 Ensure documents of external origin are identified and the distribution controlled.



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## 5.3 The Author or project coordinator shall:

- 5.3.1 Complete DCR Step 4.
- 5.3.2 Create or revise documents prior to submission for approval or reapproval.
- 5.3.3 Ensure that documents meet Quality System Criteria.
- 5.3.4 Submit completed DCR Package to the Management Representative.

#### 5.4 The **Review Team shall**:

- 5.4.1 Review the DCR Package.
- 5.4.2 Provide the Management Representative with written comments and recommendations regarding the disposition of the DCR Package.

# 5.5 The Management Representative shall:

- 5.5.1 Verify backup of all electronic data quarterly
- 5.5.2 Maintain separate current and obsolete document databases.
- 5.5.3 When receiving a DCR from the originator:
  - 5.5.3.1 Determine whether the submission is a System Level or Product Line Level document.
  - 5.5.3.2 Complete DCR Step 3,5, and 7 as indicated, if system level.
  - 5.5.3.3 Determine whether the submission is major, minor, or administrative.
  - 5.5.3.4 Determine whether the submission meets Quality System Criteria.

## 5.6 **Document Users shall**:

- 5.6.1 Check the Master List located on the QSM website <a href="http://iso9000.amc.faa.gov">http://iso9000.amc.faa.gov</a>, or "W" drive, to verify current versions of all documents.
- 5.6.2 Use and download only current documents identified on the Master List.



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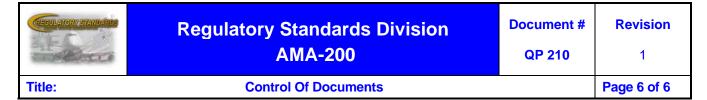
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## 6. Procedure

- 6.1 Once per quarter, the Management Representative shall notify the Leadership Team and verify that the routine backing up of systems data has been completed.
- 6.2 All document tracking, posting, and archiving shall be accomplished electronically by the Management Representative. Document tracking includes original submission and amendments to existing documents.
  - 6.2.1 Specifically, document tracking will be accomplished through the DCR form sequential numbering system, which will begin with 0001. Each DCR number is unique and shall be accounted for by the Management Representative.
- 6.3 Revisions to Quality System documents are depicted by a revision number appended to the document header. Successive revisions to documents shall use the next sequential number. The Initial release of a document will be annotated as revision "0" (zero) or original.
  - 6.3.1 In addition to the revision number placed in the header, the revision number, brief description of change, author, and effective date will be placed in the Revision History block where provided.
- 6.4 The official Master List of Quality System documents is available only at the AMA-200 web site (<a href="http://iso9000.amc.faa.gov">http://iso9000.amc.faa.gov</a>), product line documents shall be available on the "W" drive. Complete electronic versions of the documents can be accessed from these sites. The versions on the web site and "W" drive are the official controlled documents and any downloaded or printed hardcopy is uncontrolled, not subject to any amendment action, and <a href="mailto:ma
- 6.5 All documents shall be submitted for approval or re-approval, into the AMA-200 Quality System by following the six steps delineated on the DCR. Each step identifies the chain of custody for the document package. Each step shall be completed and, where appropriate, authorized before the document package can progress. The package is forwarded for each step.
  - 6.5.1 Step 1: The Originator shall obtain a DCR from the AMA-200 QSM website, complete step 1, and submit the DCR package to the Management Representative.
  - 6.5.2 Step 2: The Management Representative shall review Step 1 for accuracy and completeness.



- 6.5.2.1 If the DCR package is incomplete or inaccurate, the Management Representative shall return it to the Originator for correction and resubmission.
- 6.5.2.2 If the DCR package is acceptable, the Management Representative shall complete step 2.
- 6.5.3 Step 3: The Management Representative shall review the DCR package and assign it to a Branch (if product level), the Branch Manager shall assign an author or project coordinator.
- 6.5.4 Step 4: The Author or project coordinator shall create or revise the document(s) as appropriate, complete step 4, and forward the DCR Package to the Management Representative through the Branch Manager.
  - 6.5.4.1 The Author or project coordinator shall identify other AMA-200 documents that may be affected.
- 6.5.5 Step 5: The Management Representative shall review the DCR package, complete Step 5 as appropriate.
  - 6.5.5.1 Administrative changes: may be approved by the Management Representative without the assignment of a Review Team.
  - 6.5.5.2 Minor changes: the Management Representative or Branch Manager shall assign a Review Team to review the DCR package.
  - 6.5.5.3 Major changes: the Management Representative or Branch Manager shall implement the design and development process described in <u>Section 7</u> of AMA-200, QSM <u>2</u>00.
- 6.5.6 The DCA shall complete Step 6, as appropriate.
  - 6.5.6.1 If the DCR package is not approved by the Management Representative, the Representative shall complete the "Not Approved" section of Step 6 and return the package to the Author.
  - 6.5.6.2 If the DCR package is approved by the Management Representative, the Representative will complete the "Approved" section of Step 7.
  - 6.5.6.3 The Management Representative will insert approved original documents and/or approved revisions into the affected manual(s) identified on the DCR.



and make revisions to AMA-200 documents. The Branch Manager may assign access rights for product level documents.

- 6.7 The Management Representative shall notify all AMA-200 personnel of a revision, amendment, or any other change in any AMA-200 quality documents by e-mail when required, if affecting product quality.
- 6.8 The Management Representative shall maintain quality records on file and if possible, maintain a master backup on a CD.
- 6.9 The Management Representative (for system level) and the Branch Manager (for product level) shall archive all superceded documents, in their complete and original form, into separate folders or in their respective database site ("W" drive, web site).
  - 6.9.1 Superceded documents will be limited to "read only" status, with write access granted only to management and program managers.
  - 6.9.2 Superceded documents will include the date of archiving for future reference.
- 6.10 Superceded documents shall be archived for a period of no less than five years.

#### 7. Metrics

There are no metrics required for this document.

### 8. Quality Records

Quality Records for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
QF 210	Document Change Request (DCR)	Five Years

Quality forms are found in Appendix 1 of the AMA-200 QSM.